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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/019,588 | 12/20/2001 | Frederic Andre | SANSYL002 | 1696 |

7590 03/09/2005

Patent Department
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| EXAMINER | |
|---|---|
| FUBARA, BLESSING M | |
| **ART UNIT** | **PAPER NUMBER** |
| 1615 | |

DATE MAILED: 03/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/019,588 | ANDRE ET AL. | |
| | Examiner | Art Unit | |
| | Blessing M. Fubara | 1615 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *04 November 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1,3,4,6-9 and 11-34* is/are pending in the application.

4a) Of the above claim(s) *24 and 34* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,4,6-9,11-23 and 25-33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

Examiner acknowledges receipt of amendments and remarks filed 11/04/04. Claims 1, 3, 4, 6-9 and 11-34 are pending. Claims 24 and 34 are withdrawn form consideration.

### *Claim Rejections - 35 USC § 112*

1. The rejection of claim 17 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in light of the amendment.

### *Claim Rejections - 35 USC § 103*

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. The rejection of claims 1, 3, 4, 6-9, 11-23 and 25-33 under 35 U.S.C. 103(a) as being unpatentable over Chen et al. (US 2003/0077297) in view of Lerner et al. (US 5,840,332) is withdrawn because applicants' argument regarding the Chen reference is persuasive. The rejection of 08/11/2004 has been withdrawn.

4. Claims 1, 3, 4, 7-9 and 11-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heinicke et al. (US 5,834,024) in view of Staniforth et al. (US 5,725,883).

Heinicke discloses diltiazem tablet formulation that comprises a core that is a sphere, bead or seed of an inert ingredient and the core comprises a diltiazem, a binder, emulsifier or stabilizer and the core may further include a dispersing agent, glidant and/or surfactant (column 4, lines 27-49 and claims 3 and 4); the core is coated with EUDRAGIT RL and EUDRAGIT RS.

Heinicke discloses a general teaching of surfactants without indicating cationic, anionic or zwitterionic surfactant.

Staniforth discloses a pharmaceutical composition that comprises active agents such as diltiazem (column 15, line 10), cationic surfactant such as benzalkonium chloride (column 8, lines 29 and 47) and microcrystalline cellulose (abstract; column 4, line 60).

Heinicke discloses the formulation except that a general disclosure of surfactant is made. Staniforth is relied upon for a disclosure where diltiazem containing formulation comprises benzalkonium chloride cationic surfactant. Regarding the amount of the surfactant, a skilled artisan or the person of ordinary skill in the art would incorporate amount of surfactant necessary as surface-active agent. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare the formulation of Heinicke and to use a benzalkonium chloride cationic surfactant with the diltiazem according to Staniforth with expectation of a controlled release dosage for.

5. Claims 1, 3, 4, 6-9, 11-23 and 25-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilson et al. (US 6,403,597).

Wilson discloses a composition that comprises effective amount of an active agent, pharmaceutically acceptable carrier or vehicle, excipients and/or surfactants and/or preservatives and/or stabilizers and/or chelating agents (column 5, lines 32-43) and EUDRAGIT RS sustained release carrier (column 16, line 31) and the sustained release over an extended period may or may not be delayed release (column 16, lines 5-7). The composition can be formulated with any number of the drugs listed in column 8, line 36 to column 13 line 50; one of the drugs listed is alfuzosin (column 13, line 32). The surfactant may be anionic, cationic, amphoteric or non-

ionic (column 15, lines 33-35) and in column 20, line 36, benzalkonium chloride is added to formulation as an antimicrobial preservative that is for inhalation therapy. Specifically, Wilson's composition comprises phosphodiesterase and one or more of the active agents listed in column 11, line 58 to column 13 line 50 can be administered with the phosphodiesterase. The formulation of Wilson also contains binders such as polyvinylpyrrolidone and hydroxypropyl methylcellulose (column 15, lines 12-14) and diluents, lubricants and fillers (column 15, lines 17, 20 and 27). Wilson discloses that any of the active agents may be administered in the form of salts and maleic acid, fumaric acid, succinic acid, tartaric acid and citric acids are use to prepare the acid addition salts (column 13, line 51 to column 14 line 8). The pharmaceutical composition of Wilson is formulated into tablet, capsule, caplet, gel caps, suspension and powder dosage forms (column 14, lines 37-43). The list of drugs listed is long but the list is not an infinite number of drugs. The drugs are listed according to the function of the drug so that it would not be burdensome on the artisan to combine a particular active agent with the phosphodiesterase according the desired treatment and the list is not exhaustive.

Wilson discloses a formulation that comprises active agent, sustained release carrier, phosphodiesterase, surfactant and excipients. Regarding the percent amount of the surfactant relative to the EUDRAGIT sustained release carrier, it is noted that there is no demonstration in applicants specification showing that the recited percent amount of the surfactant provides unusual results and a skilled artisan or person of ordinary skill in the art have the skills to incorporated amounts of surfactants effective as surface active agent in the composition. While Wilson discloses that the composition may contain benzalkonium chloride, Wilson does not disclose cetylpyridinium chloride. However, benzalkonium chloride and cetylpyridinium

chloride are equivalent and one can be used in place of the other since they are equivalent. This equivalency is evident in a teaching reference to Nishihata et al. (US 6,020,375) where Nishihata discloses a bactericidal composition that comprises the **surfactant** and the surfactant is at least one selected from the group consisting of polysorbate 80, polyoxyethylene hydrogenated castor oil, polyoxyl 40 stearate, polyoxyethylene laurylether, sodium lauroyl sarcosinate, lauroyl-L-glutamic acid triethanolamine salt, sodium myristyl sarosinate, **benzalkonium chloride**, benzethonium chloride, **cetylpyridinium chloride**, cetyltrimethylammonium chloride lauryl dimethylaminoacetic betaine, 2-alkyl-N-carboxymethyl-N-hydroxyethylimidazolinium betaine, and alkyldiaminoglycine hydrochloride.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare and administer the composition of Wilson and substituting one surfactant for the other without altering the property of the composition.

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Mughal et al. (US 4,524,060) discloses sustained release pharmaceutical composition that comprises active agent, wetting agent or surfactant, disintergrants and EUDRAGIT RL and RS enteric coating (abstract; column 2, lines 10-18; column 3, lines 6-38). Staniforth et al (US 5,858,412) discloses sustained release formulation comprising active agents, microcrystalline cellulose, cationic surfactant, EUDRAGIT RL and EUDRAGIT RS sustained release coatings (column 10, lines 17-33 and 53-58; column 1, lines 15-34 and 59-63; column 20, lines 17-32; column 21, lines 13-18; column 22, lines 14-22) Mughal and Staniforth (US 5,858,412) are equal importance as the references cited above.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-272-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Blessing Fubara
Patent Examiner
Tech. Center 1600